ACIPHEX- rabeprazole 20mg tablet, delayed release
Advanced Rx Pharmacy of Tennessee, LLC

Rabeprazole 20mg tablets #60

Medication Guide Section

MEDICATION GUIDE

Rabeprazole Sodium (ra-BEP-ra-zole SOE-dee-um)

Delayed-Release Tablets

What is the most important information I should know about rabeprazole sodium delayed-release tablets?

You should take rabeprazole sodium delayed-release tablets exactly as prescribed, at the lowest dose possible and for the shortest time needed.

Rabeprazole sodium delayed-release tablets may help your acid-related symptoms, but you could still have serious stomach problems. Talk with your doctor.

Rabeprazole sodium delayed-release tablets can cause serious side effects, including:

· A type of kidney problem (acute interstitial nephritis). Some people who take proton pump inhibitor (PPI) medicines, including rabeprazole sodium delayed-release tablets, may develop a kidney problem called acute interstitial nephritis that can happen at any time during treatment with rabeprazole sodium delayed-release tablets. Call your doctor right away if you have a decrease in the amount that you urinate or if you have blood in your urine.

· Diarrhea caused by an infection (Clostridium difficile) in your intestines. Call your doctor right away if you have watery stools or stomach pain that does not go away. You may or may not have a fever.

· Bone fractures (hip, wrist, or spine). Bone fractures in the hip, wrist, or spine may happen in people who take multiple daily doses of PPI medicines and for a long period of time (a year or longer). Tell your doctor if you have a bone fracture, especially in the hip, wrist, or spine.

· Certain types of lupus erythematosus. Lupus erythematosus is an autoimmune disorder (the body’s immune cells attack other cells or organs in the body). Some people who take PPI medicines, including rabeprazole sodium delayed-release tablets, may develop certain types of lupus erythematosus or have worsening of the lupus they already have. Call your doctor right away if you have new or worsening joint pain or a rash on your cheeks or arms that gets worse in the sun.

Talk to your doctor about your risk of these serious side effects.

Rabeprazole sodium delayed-release tablets can have other serious side effects. See “What are the possible side effects of rabeprazole sodium delayed-release tablets?”

What is rabeprazole sodium delayed-release tablet?

Rabeprazole sodium delayed-release tablets is a prescription medicine called a proton

pump inhibitor (PPI).

Rabeprazole sodium delayed-release tablets reduces the amount of acid in your stomach.

In adults, Rabeprazole sodium delayed-release tablets is used for:

· 8 weeks up to 16 weeks to heal acid-related damage to the lining of the esophagus (called erosive esophagitis or EE) and to relieve symptoms, such as heartburn pain.

· maintaining healing of the esophagus and relief of symptoms related to EE. It is not known if rabeprazole sodium delayed-release tablets is safe and effective if used longer than 12 months (1 year).

· up to 4 weeks to treat daytime and nighttime heartburn and other symptoms that happen with Gastroesophageal Reflux Disease (GERD).

· up to 4 weeks for the healing and relief of symptoms of duodenal ulcers.

· 7 days with certain antibiotic medicines to treat an infection and stomach (duodenal) ulcers caused by bacteria called H. pylori.

· the long-term treatment of conditions where your stomach makes too much acid. This includes a rare condition called Zollinger-Ellison syndrome.

In adolescents 12 years of age and older, rabeprazole sodium delayed-release tablets is used for up to 8 weeks to treat symptoms of GERD.

It is not known if rabeprazole sodium delayed-release tablets is safe and effective in children less than 12 years of age for other uses. Rabeprazole sodium delayed-release tablets should not be used in children under 12 years of age.

Do not take rabeprazole sodium delayed-release tablets if you are:

· allergic to rabeprazole, any other PPI medicine, or any of the ingredients in rabeprazole sodium delayed-release tablets. See the end of this Medication Guide for a complete list of ingredients.

· taking a medicine that contains rilpivirine (EDURANT, COMPLERA, ODEFSEY) used to treat HIV-1 (Human Immunodeficiency Virus).

Before you take rabeprazole sodium delayed-release tablets, tell your doctor about all of your medical conditions, including if you:

· have low magnesium levels in your blood.

· have liver problems.

· are pregnant or plan to become pregnant. It is not known if rabeprazole sodium delayed-release tablets can harm your unborn baby.

· are breastfeeding or plan to breastfeed. It is not known if rabeprazole sodium delayed-release tablets passes into your breast milk. Talk to your doctor about the best way to feed your baby if you take rabeprazole sodium delayed-release tablets

Tell your doctor about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Especially tell your doctor if you take an antibiotic that contains clarithromycin or amoxicillin or if you take warfarin (COUMADIN, JANTOVEN), methotrexate (OTREXUP, RASUVO, TREXALL, XATMEP),

digoxin (LANOXIN), or a water pill (diuretic).

How should I take rabeprazole sodium delayed-release tablets?

Take rabeprazole sodium delayed-release tablets exactly as prescribed.

· Rabeprazole sodium delayed-release tablets is usually taken 1 time each day. Your doctor will tell you the time of day to take rabeprazole sodium delayed-release tablets, based on your medical condition.

· Rabeprazole sodium delayed-release tablets can be taken with or without food. Your doctor will tell you whether to take this medicine with or without food based on your medical condition.

· Swallow each rabeprazole sodium delayed-release tablets tablet whole. Do not chew, crush, or split rabeprazole sodium delayed-release tablets tablets. Tell your doctor if you cannot swallow tablets whole.

· If you miss a dose of rabeprazole sodium delayed-release tablets, take it as soon as possible. If it is almost time for your next dose, you should not take the missed dose. You should take your next dose at your regular time. Do not take 2 doses at the same time.

· If you take too much rabeprazole sodium delayed-release tablets, call your doctor or your poison control center at 1-800-222-1222 right away, or go to the nearest emergency room.

· If your doctor prescribes antibiotic medicines with rabeprazole sodium delayed-release tablets, read the patient information that comes with the antibiotic medicines before you take them.

What are the possible side effects of rabeprazole sodium delayed-release tablets?

rabeprazole sodium delayed-release tablets can cause serious side effects, including:

· See “What is the most important information I should know about rabeprazole sodium delayed-release tablets?”

· Interaction with warfarin.

Taking warfarin with a PPI medicine may lead to an increased risk of bleeding and death. If you take warfarin, your doctor may check your blood to see if you have an increased risk of bleeding. If you take warfarin during treatment with rabeprazole sodium delayed-release tablets, tell your doctor right away if you have any signs or symptoms of bleeding, including:
o pain, swelling or discomfort
o menstrual bleeding that is heavier than normal
o headaches, dizziness, or weakness
o pink or brown urine
o unusual bruising (bruises that happen without known cause or that grow in size)
o red or black stools
o nosebleeds
o coughing up blood
o bleeding gums
o vomiting blood or vomit that looks like coffee grounds
o bleeding from cuts take a long time to stop

· Low vitamin B-12 levels in the body can happen in people who have taken rabeprazole sodium delayed-release tablets for a long time (more than 3 years). Tell your doctor if you have symptoms of low vitamin B-12 levels, including shortness of breath, lightheadedness, irregular heartbeat, muscle weakness, pale skin, feeling tired, mood changes, and tingling or numbness in the arms and legs.

· Low magnesium levels in the body

can happen in people who have taken rabeprazole sodium delayed-release tablets for at least 3 months. Tell your doctor if you have symptoms of low magnesium levels, including seizures, dizziness, irregular heartbeat, jitteriness, muscle aches or weakness, and spasms of hands, feet or voice.

· Stomach growths (fundic gland polyps). People who take PPI medicines for a long time have an increased risk of developing a certain type of stomach growths called fundic gland polyps, especially after taking PPI medicines for more than 1 year.

The most common side effects of rabeprazole sodium delayed-release tablets in adults include: pain, sore throat, gas, infection, and constipation.

The most common side effects of rabeprazole sodium delayed-release tablets in adolescents 12 years of age and older include: headache, diarrhea, nausea, vomiting, and stomach-area (abdomen) pain.

These are not all of the possible side effects of rabeprazole sodium delayed-release tablets. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088

How should I store rabeprazole sodium delayed-release tablets?

Store rabeprazole sodium delayed-release tablets in a dry place at room temperature between 68°F to 77°F (20°C to 25°C).

Keep rabeprazole sodium delayed-release tablets and all medicines out of the reach of children.

General Information about the safe and effective use of rabeprazole sodium delayed-release tablets

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use rabeprazole sodium delayed-release tablets for a condition for which it was not prescribed. Do not give rabeprazole sodium delayed-release tablets to other people, even if they have the same symptoms that you have. It may harm them.

You can ask your doctor or pharmacist for information about rabeprazole sodium delayed-release tablets that is written for health professionals.

What are the ingredients in rabeprazole sodium delayed-release tablets?

Active ingredient: rabeprazole sodium

Inactive ingredients:Mannitol, Crospovidone, Magnesium Oxide Light, Hydroxy Propyl Cellulose, Sodium Stearyl Fumarate, Magnesium Stearate, Ethyl Cellulose, Hypromellose phthalate, Carnauba Wax, Diacetylated Monoglyceride. The coating material contains Polyvinyl Alcohol, Talc, Titanium Dioxide, Macrogol, Lecithin and Iron Oxide Yellow. The printing ink contains Shellac, Ferrosoferric Oxide, Propylene Glycol and Ammonium Hydroxide 28%.

This Medication Guide has been approved by the U.S. Food and Drug Administration.
Manufactured by:

Alkem Laboratories Ltd.

Mumbai - 400 013, INDIA

Distributed by:

Ascend Laboratories, LLC

Parsippany, NJ 07054

Revised: December, 2018

Dosage and Administration Section

2 DOSAGE & ADMINISTRATION

Table 1 shows the recommended dosage of rabeprazole sodium delayed-release tablets in adults and adolescent patients 12 years of age and older. The use of rabeprazole sodium delayed-release tablets is not recommended for use in pediatric patients 1 year to less than 12 years of age because the lowest available tablet strength (20 mg) exceeds the recommended dose for these patients. Use another rabeprazole formulation for pediatric patients 1 year to less than 12 years of age.

Table 1: Recommended Dosage and Duration of Rabeprazole sodium delayed-release tablets in Adults and Adolescents 12 Years of Age and Older

Indication
Dosage of Rabeprazole sodium delayed-release tablets
Treatment Duration
Adults
Healing of Erosive or Ulcerative Gastroesophageal Reflux Disease (GERD)
20 mg once daily
4 to 8 weeks*
Maintenance of Healing of Erosive or Ulcerative GERD
20 mg once daily
Controlled studies do not extend beyond 12 months
Symptomatic GERD in Adults
20 mg once daily
Up to 4 weeks**
Healing of Duodenal Ulcers
20 mg once daily after the morning meal
Up to 4 weeks***
Helicobacter pylori Eradication to Reduce the Risk of Duodenal Ulcer Recurrence
Rabeprazole sodium delayed-release tablets 20 mg Amoxicillin 1000 mg Clarithromycin 500 mg Take all three medications twice daily with morning and evening meals; it is important that patients comply with the full 7-day regimen [see Clinical Studies (14.5)]
7 days
Pathological Hypersecretory Conditions, Including Zollinger-Ellison Syndrome
Starting dose 60 mg once daily then adjust to patient needs; some patients require divided doses Dosages of 100 mg once daily and 60 mg twice daily have been

administered
As long as clinically indicated Some patients with Zollinger-Ellison syndrome have been treated continuously for up to one year
Adolescents 12 Years of Age and Older
Symptomatic GERD
20 mg once daily
Up to 8 weeks

* For those patients who have not healed after 8 weeks of treatment, an additional 8-week course of rabeprazole sodium delayed-release tablets may be considered.

** If symptoms do not resolve completely after 4 weeks, an additional course of treatment may be considered.

*** Most patients heal within 4 weeks; some patients may require additional therapy to achieve healing.

Administration Instructions

• Swallow rabeprazole sodium delayed-release tablets whole. Do not chew, crush, or split tablets.

• For the treatment of duodenal ulcers take rabeprazole sodium delayed-release tablets after a meal.

• For Helicobacter pylori eradication take rabeprazole sodium delayed-release tablets with food.

• For all other indications rabeprazole sodium delayed-release tablets can be taken with or without food.

Take a missed dose as soon as possible. If it is almost time for the next dose, skip the missed dose and go back to the normal schedule. Do not take two doses at the same time.

Indications and Usage Section

1 INDICATIONS & USAGE

1.1 Healing of Erosive or Ulcerative GERD in Adults

Rabeprazole sodium delayed-release tablets are indicated for short-term (4 to 8 weeks) treatment in the healing and symptomatic relief of erosive or ulcerative gastroesophageal reflux disease (GERD). For those patients who have not healed after 8 weeks of treatment, an additional 8-week course of rabeprazole sodium delayed-release tablets may be considered.

1.2 Maintenance of Healing of Erosive or Ulcerative GERD in Adults

Rabeprazole sodium delayed-release tablets are indicated for maintaining healing and reduction in relapse rates of heartburn symptoms in patients with erosive or ulcerative gastroesophageal reflux disease (GERD Maintenance). Controlled studies do not extend beyond 12 months.

1.3 Treatment of Symptomatic GERD in Adults

Rabeprazole sodium delayed-release tablets are indicated for the treatment of daytime

and nighttime heartburn and other symptoms associated with GERD in adults for up to 4 weeks.

1.4 Healing of Duodenal Ulcers in Adults

Rabeprazole sodium delayed-release tablets are indicated for short-term (up to four weeks) treatment in the healing and symptomatic relief of duodenal ulcers. Most patients heal within four weeks.

1.5 Helicobacter pylori Eradication to Reduce the Risk of Duodenal Ulcer Recurrence in Adults

Rabeprazole sodium delayed-release tablets, in combination with amoxicillin and clarithromycin as a three drug regimen, are indicated for the treatment of patients with H. pylori infection and duodenal ulcer disease (active or history within the past 5 years) to eradicate H. pylori. Eradication of H. pylori has been shown to reduce the risk of duodenal ulcer recurrence.

In patients who fail therapy, susceptibility testing should be done. If resistance to clarithromycin is demonstrated or susceptibility testing is not possible, alternative antimicrobial therapy should be instituted [SEE CLINICAL PHARMACOLOGY (12.2)and the full prescribing information for clarithromycin].

1.6 Treatment of Pathological Hypersecretory Conditions, Including Zollinger-Ellison Syndrome in Adults

Rabeprazole sodium delayed-release tablets are indicated for the long-term treatment of pathological hypersecretory conditions, including Zollinger-Ellison syndrome.

1.7 Treatment of Symptomatic GERD in Adolescent Patients 12 Years of Age and Older

Rabeprazole sodium delayed-release tablets are indicated for the treatment of symptomatic GERD in adolescents 12 years of age and above for up to 8 weeks.

Principal Display Panel

ACIPHEX

rabeprazole 20mg tablet, delayed release

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:80425-0134(NDC:67877-443)

Route of Administration	ORAL

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
RABEPRAZOLE SODIUM (UNII: 3L36P16U4R) (RABEPRAZOLE - UNII:32828355LL)	RABEPRAZOLE SODIUM	20 mg

Product Characteristics			
Color	yellow	**Score**	no score
Shape	ROUND	**Size**	8mm
Flavor		**Imprint Code**	20
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:80425-0134-2	60 in 1 BOTTLE; Type 0: Not a Combination Product	04/27/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA208644	04/27/2018	

Labeler - Advanced Rx Pharmacy of Tennessee, LLC (117023142)

Establishment

Name	Address	ID/FEI	Business Operations
Advanced Rx Pharmacy of Tennessee, LLC		117023142	repack(80425-0134)

Revised: 3/2021 Advanced Rx Pharmacy of Tennessee, LLC